108TH CONGRESS
2D SESSION

# S. _____

IN THE SENATE OF THE UNITED STATES

Mr. GREGG (for himself and Mr. SMITH, Ms. COLLINS, Mr. COLEMAN, and Mr. SESSIONS) introduced the following bill; which was read twice and referred to the Committee on _____

# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to protect the public health from the unsafe importation of prescription drugs and from counterfeit prescription drugs, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the ''Safe Importation of Medical Products and Other Rx Therapies Act of 2004'' or the ''Safe IMPORT Act of 2004''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

**SEC. 2. IMPORTATION.**

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) by inserting after the chapter heading the following:

''SUBCHAPTER A—GENERAL PROVISIONS''; and

(2) by adding at the end the following:

''SUBCHAPTER B—IMPORTATION OF PRESCRIPTION DRUGS

**''SEC. 811. DEFINITIONS.**

''In this subchapter:

''(1) DRUG IMPORTATION FACILITY.—The term 'drug importation facility' means a person, other than an individual importing a prescription drug under section 812, located outside the United States

(other than a transporter) that engages in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States.

''(2) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person, other than an individual importing a prescription drug under section 812, that offers to dispense in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(3) PHARMACY.—The term 'pharmacy' means a person, other than an individual importing a prescription drug under section 812, licensed by a State to dispense prescription drugs or to provide pharmaceutical care.

''(4) PERMITTED COUNTRY.—

''(A) IN GENERAL.—The term 'permitted country' means a country that—

''(i) was a member of the European Union as of December 31, 2003; and

"(ii) is designated by the Secretary as a permitted country under subparagraph (B).

"(B) REPORT.—Three years after the date of enactment of this subchapter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on Energy and Commerce of the House of Representatives a report that includes—

"(i) a list of countries under subparagraph (A)(i) designated by the Secretary from which a prescription drug shall be permitted to be imported into the United States under this subchapter, and the basis for the Secretary's determination that the importation of a prescription drug from such countries would not present an increased risk to the public health;

"(ii) a list of countries under subparagraph (A)(i) from which a prescription drug shall not be permitted to be imported into the United States under this subchapter, and the basis for Secretary's determination that the importation of a pre-

scription drug from such countries would present an increased risk to the public health;

''(iii) for countries identified in clause (i), any additional measures that could be taken to ensure that there will be no increased risk to the public health; and

''(iv) for countries identified in clause (ii), any additional measures that could be taken to a avoid, reduce, or mitigate such increased risk to the public health.

''(C) DETERMINATION.—The Secretary may determine whether to designate a permitted country at any time after submission of the report under subparagraph (B).

''(5) PRESCRIPTION DRUG.—

''(A) IN GENERAL.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(B) EXCLUSIONS.—The term 'prescription drug' does not include—

''(i) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(ii) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(iii) an infused drug (including a peritoneal dialysis solution);

"(iv) an intravenously injected drug;

"(v) a drug that is inhaled during surgery;

"(vi) a parenteral drug;

"(vii) a drug manufactured through 1 or more biotechnology processes, including—

"(I) a therapeutic DNA plasmid product;

"(II) a therapeutic synthetic peptide product of not more than 40 amino acids;

"(III) a monoclonal antibody product for in vivo use; and

"(IV) a therapeutic recombinant DNA-derived product;

"(viii) a drug required to be refrigerated at any time during manufacturing, packing, processing, or holding; or

"(ix) a photoreactive drug.

"(6) TREATING PROVIDER.—The term 'treating provider' means a licensed health care provider that—

"(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual to establish the diagnosis for which a prescription drug is prescribed;

"(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

"(iii) maintains contemporaneous medical records concerning the individual; or

"(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

"(7) WHOLESALER.—

"(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States as described in section 503(e)(2).

"(B) EXCLUSION.—The term 'wholesaler' does not include—

''(i) a person authorized to import drugs under section 801(d)(1); or

''(ii) an individual importing a prescription drug under section 812.

**''SEC. 812. PERSONAL IMPORTATION.**

''(a) IN GENERAL.—An individual may import a prescription drug from Canada or a permitted country into the United States for personal use (not for resale), subject to subsections (b) and (c).

''(b) IMPORTATION.—An individual may import a prescription drug if—

''(1) the prescription drug is purchased from a licensed pharmacy in Canada or a licensed pharmacy in a permitted country and dispensed in compliance with the applicable laws of Canada or the permitted country regarding the practice of pharmacy;

''(2) the prescription drug is imported for personal use (not for resale) by the individual;

''(3) the prescription drug is imported from Canada or a permitted country into the United States;

''(4) the prescription drug is imported by the individual on the person of the individual;

''(5) the quantity of the prescription drug imported does not exceed a 90-day supply during any 90-day period; and

''(6) the prescription drug is accompanied by—

''(A) a copy of a prescription valid in a State and cosigned by a prescribing physician in Canada or the permitted country; or

''(B) if the prescription drug is available in Canada or the permitted country without a prescription, a copy of the valid prescription signed by a pharmacist licensed in Canada or the permitted country.

''(c) COMPASSIONATE USE.—The Secretary may permit an individual to import an up to a 90-day supply of a drug that is not approved by the Secretary under section 505 if the importation is for continuation of personal use by the individual for treatment, begun in a foreign country, of a serious medical condition.

**''SEC. 813. PHARMACY AND WHOLESALER IMPORTATION OF PRESCRIPTION DRUGS.**

''(a) IN GENERAL.—

''(1) IMPORTATION.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler may import a prescription drug from Canada or a permitted country into the United States for dispensing

in the United States in accordance with this subchapter.

''(2) LIMITATION TO CERTAIN PORTS.—The Secretary may limit the ports of entry in the United States through which a prescription drug may be imported under this section to a reasonable number of ports designated by the Secretary.

''(b) REQUIREMENTS.—Each prescription drug imported under this subchapter shall—

''(1) be approved under section 505;

''(2) comply with sections 501 and 502;

''(3) be in a container that bears a label stating, in prominent and conspicuous type—

''(A) the lot number of the prescription drug;

''(B) the name, address and phone number of the drug importation facility;

''(C) the following: 'This drug has been imported from _____.', with the name of the permitted country from which the prescription drug is imported in the blank space; and

''(D) a unique identifier code provided by the Secretary that modifies the national drug code of the prescription drug to indicate that the drug has been imported; and

''(4) comply with any other applicable requirement of this Act.

''(c) APPROVED LABELING.—

''(1) IN GENERAL.—A drug importation facility that offers for importation a prescription drug under this subchapter shall submit to the Secretary an application for approval that demonstrates that the labeling of the prescription drug to be imported into the United States complies with the requirements of sections 502 and 503.

''(2) PROCEDURE.—Not later than 60 days after receipt of a completed application under paragraph (1), the Secretary shall—

''(A) approve or deny the application consistent with the requirements of sections 502 and 503; and

''(B) notify the applicant of the decision of the Secretary and, if the application is denied, the reason for the denial.

''(3) LISTS.—

''(A) APPLICATIONS.—The Secretary shall maintain an updated list of applications pending, applications approved, and applications denied under this subsection.

"(B) PORTS.—The Secretary shall maintain an updated list of ports through which a prescription drug may be imported under this section and make the list available to the public on an Internet website.

"(d) PROHIBITION OF IMPORTATION OF A PRESCRIPTION DRUG THAT ENTERS OTHER COUNTRIES.—

"(1) IN GENERAL.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler shall not import a prescription drug if, during any period in which the prescription drug was not in the control of the manufacturer, the prescription drug entered a country other than—

"(A) Canada; or

"(B) subject to paragraph (2), a country that was a member of the European Union as of December 31, 2003.

"(2) LIMITATION.—The Secretary may exclude 1 or more of the countries under subparagraph (B) of paragraph (1) from the application of that subparagraph if the Secretary determines that allowing a prescription drug to be imported into the United States after having entered that country outside control of a manufacturer would present a risk to the public health.

''(e) PROHIBITION OF COMMINGLING.—

''(1) IN GENERAL.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler shall not commingle a prescription drug imported into the United States under this subchapter with a prescription drug that is not imported from Canada or a permitted country.

''(2) LABEL.—A pharmacy or Internet pharmacy that dispenses a prescription drug imported from Canada or a permitted country shall affix on each dispensed container of the prescription drug the label required under subsection (b)(3) unless such a label is already affixed to the container.

''(f) DRUG RECALLS.—On receipt of notification from the manufacturer of a prescription drug imported from Canada or a permitted country under this section that the prescription drug has been recalled or withdrawn from the market in Canada or a permitted country, a drug importation facility shall promptly provide the Secretary and any person to whom the prescription drug was distributed a notice that the drug has been recalled or withdrawn from the market and that includes—

''(1) information (including the lot number) that identifies the prescription drug; and

''(2) a statement of the reason for the recall or withdrawal.

''(g) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge or a nominal charge by the manufacturer of the prescription drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(h) JURISDICTION.—The district courts of the United States shall have jurisdiction in an action brought by the United States against a person importing or offering for importation a prescription drug in violation of the requirements of this section.

''(i) EFFECT OF SECTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs (including the interdiction of prescription drugs that are unapproved, adulterated, or misbranded), other than with respect to section 801(d)(1) as provided in subsection (g).''.

(b) REGULATIONS.—

(1) PERSONAL IMPORTATION.—

(A) IN GENERAL.—The Secretary of Health and Human Services may promulgate

regulations to carry out section 812 of the Federal Food, Drug, and Cosmetic Act (as added by this section).

(B) EFFECTIVE DATE.—Section 812 of the Federal Food, Drug, and Cosmetic Act shall take effect on the date of enactment of this Act, without regard to whether the Secretary of Health and Human Services has promulgated regulations under paragraph (1).

(2) PHARMACY AND WHOLESALER IMPORTATION OF PRESCRIPTION DRUGS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall promulgate interim final regulations to carry out section 813 of the Federal Food, Drug, and Cosmetic Act (as added by this section).

(B) EFFECTIVE DATE.—Section 813 of the Federal Food, Drug, and Cosmetic Act shall take effect on the date that is 1 year after the date of enactment of this Act, without regard to whether the Secretary of Health and Human Services has promulgated regulations under paragraph (1).

(c) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) Dispensing or offering to dispense a prescription drug imported into the United States in violation of the requirements of section 813.''.

**SEC. 3. PROTECTION AGAINST ADULTERATED PRESCRIPTION DRUGS.**

Section 801(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(h)) is amended—

(1) in paragraph (2)—

(A) by inserting ''and prescription drugs'' after ''related to foods'';

(B) by inserting ''and of prescription drugs'' after ''adulteration of food,''; and

(C) by inserting ''and prescription drugs'' after ''importation of food''; and

(2) in paragraph (3), by inserting ''and for ensuring the safety of imported prescription drugs'' after ''food safety''.

**SEC. 4. INTERNET PHARMACIES.**

(a) INTERNET PHARMACIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

**"SEC. 511. INTERNET PHARMACIES.**

"(a) DEFINITIONS.—In this section:

"(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

"(2) DESIGNATED PAYMENT SYSTEM.—

"(A) IN GENERAL.—The term 'designated payment system' means a system used by a person to effect a credit transaction, electronic transfer, or money transmitting service described in subparagraph (B) that the Federal functional regulators determine, by regulation or order, could be used in connection with, or to facilitate, a restricted transaction.

"(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

"(i) a creditor;

"(ii) a credit card issuer;

"(iii) a financial institution;

"(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

"(v) a money transmitting business; or

"(vi)(I) an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service; or

"(II) any participant in a network described in subclause (I).

"(3) FEDERAL FUNCTIONAL REGULATOR.—The term 'Federal functional regulator' has the meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).

"(4) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

"(5) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that dispenses or offers to dispense a prescription drug through an Internet website in interstate commerce in the United States regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(6) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual who placed the unlawful Internet request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual who placed the unlawful Internet request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual who placed the unlawful Internet request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Federal functional regulators by regulation) that in-

volves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual who placed the unlawful Internet request.

''(7) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(8) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor'; and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602)

''(B) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer'—

''(i) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) includes any fund transfer covered under Article 4A of the Uniform

Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(b) IN GENERAL.—An Internet pharmacy may only dispense or offer to dispense a prescription drug to a person in the United States in accordance with this section.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—To be licensed under this section an Internet pharmacy shall—

''(A) have its principal place of business in the United States, Canada, or a permitted country; and

"(B) be licensed by the Secretary in accordance with this section prior to dispensing a prescription drug to an individual.

"(2) CONDITIONS FOR LICENSING.—

"(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application that includes—

"(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

"(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

"(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

"(II) in the case of an Internet pharmacy located in Canada or a permitted country, verification that—

"(aa) all employees and agents of the Internet pharmacy are in compliance with applicable laws of Canada or the permitted country regarding the practice of pharmacy, including licensing laws and inspection requirements; and

"(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

"(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

"(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities

and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Internet pharmacy is in compliance with this subsection; and

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void.

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall provide to any person that accesses the Internet pharmacy website, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States or countries, as appropriate, in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

"(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription.

"(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

"(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

"(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

"(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient prior to and subse-

quent to the time at which the Internet pharmacy dispenses the drug.

"(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

"(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

"(vi) Develop a system to inform caregivers and patients about drug recalls.

"(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

"(viii) Assure that the sale of a prescription drug is in accordance with a prescription from the treating provider of the individual.

"(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

"(aa) Receiving from the individual or treating provider of the individual the prescription of the individual by mail (including a private

carrier), or receiving from the treating provider of the individual the prescription of the individual by electronic mail.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)), confirming with the treating provider the information in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the

prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(4) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a completed licensing application under paragraph (3), the Secretary shall—

''(i) assign an identification number to each Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensure application; and

''(iii) not later than 60 days after receipt of the licensure application, issue a license if the Internet pharmacy is in compliance with conditions under paragraph (3).

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensure application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensure applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(5) LIST.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a list of licensees.

''(B) AVAILABILITY.—The Secretary shall make the list described under subparagraph (A) and information submitted by the licensee under paragraph (3)(B) available to the public on an Internet website and through a toll-free telephone number.

"(6) LICENSING FEE.—The Secretary shall establish a licensing fee that an Internet pharmacy licensed by the Secretary under this section shall be required to pay to the Secretary.

"(A) COLLECTION.—

"(i) COLLECTION OF INITIAL YEAR LICENSING FEE.—A licensing fee of $5,000 shall be payable for the fiscal year in which the Internet pharmacy first submits a licensing application under this section.

"(ii) COLLECTION IN SUBSEQUENT YEARS.—After the licensing fee is paid for the first fiscal year, the fee, as modified under subparagraph (B), shall be payable on or before October 1 of each year.

"(iii) ONE FEE PER INTERNET PHARMACY.—The licensing fee shall be paid only once for each Internet pharmacy for a fiscal year in which the fee is payable.

"(B) FEE AMOUNT.—The amount of the licensing fee shall be determined each year by the Secretary based on the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

"(C) ANNUAL FEE DETERMINATION.—

"(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2004, the Secretary shall determine the licensing fee for that fiscal year.

"(ii) PUBLICATION OF FEE AMOUNT.—Not later than 60 days before each fiscal year, the Secretary shall publish the licensing fee under this section for that fiscal year and provide for a period of 30 days for the public to provide written comments on the fee.

"(D) USE OF FEES.—The licensing fees collected under this section shall be used, without further appropriation, to carry out this section.

"(E) FAILURE TO PAY FEE.—

"(i) DUE DATE.—A licensing fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

"(ii) FAILURE TO PAY.—If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary

shall not permit the Internet pharmacy to engage in the dispensing of drugs as described under this section until all such fees owed by the Internet pharmacy are paid.

''(F) REPORTS.—Beginning with fiscal year 2005, not later than 60 days after the end of each fiscal year during which licensing fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(i) implementation of the licensing fee authority during the fiscal year; and

''(ii) the use by the Secretary of the licensing fees collected during the fiscal year for which the report is made.

''(7) TERMINATION OF LICENSE.—The Secretary, upon the initiative of the Secretary, may terminate a license issued under subsection (c), after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that an Internet pharmacy—

"(A) has demonstrated a pattern of noncompliance with this section;

"(B) has made an untrue statement of material fact in its license application; or

"(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

"(8) RENEWAL EVALUATION.—

"(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection pursuant to the submission of a renewal application, the Secretary shall conduct an evaluation to determine whether the Internet pharmacy is in compliance with this section.

"(B) EVALUATION.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

"(9) CONTRACT FOR OPERATION OF PROGRAM.—

"(A) IN GENERAL.—The Secretary may award a contract under this subsection for the operation of the licensing program.

"(B) TERM.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewable.

"(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

"(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—A provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f))) or an advertising service provider shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing of a prescription drug if the provider of the service—

"(1) accepts advertising for a prescription drug from an unlicensed Internet pharmacy; or

"(2) accepts advertising stating that an individual does not need a physician's prescription to obtain a prescription drug.

"(e) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.—

"(1) REGULATIONS.—Not later than 1 year after the date of enactment of this section, the Federal functional regulators shall promulgate regulations requiring a person described in subsection (a)(2) to prevent restricted transactions by establishing policies and procedures that—

"(A)(i) are reasonably designed to allow the payment system and any person involved in the payment system to identify restricted transactions by means of codes in authorization messages or by other means; and

"(ii) are reasonably designed to block restricted transactions identified as a result of the policies and procedures developed under clause (i); or

"(B) prevent the acceptance of the products or services of the payment system in connection with a restricted transaction.

"(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Federal functional regulators shall—

''(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to identify and reasonably designed to block or to prevent the acceptance of the products or services in connection with each type of restricted transaction, including—

''(i) identifying transactions by a code or codes in the authorization message; and

''(ii) denying authorization of a credit card transaction in response to an authorization message; and

''(B) to the extent practicable, permit any participant in a designated payment system to choose among alternative means of identifying and blocking, or otherwise preventing the acceptance of the products or services of the designated payment system or participant in connection with, restricted transactions.

''(3) COMPLIANCE WITH PAYMENT SYSTEM POLICIES AND PROCEDURES.—A person described in subsection (a)(2)(B) meets the requirement of paragraph (1) if—

''(A) the person relies on and complies with the policies and procedures of a designated

payment system of which the person is a member or in which the person is a participant, to—

"(i) identify and block restricted transactions; or

"(ii) otherwise prevent the acceptance of the products or services of the payment system, member, or participant in connection with restricted transactions; and

"(B) such policies and procedures of the designated payment system comply with the requirements of regulations promulgated under paragraph (1).

"(4) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—A person that is subject to a regulation or an order issued under this section and blocks or otherwise refuses to honor a restricted transaction (or a transaction that such person reasonably believes to be a restricted transaction) or as a member of a designated payment system, relies on the policies and procedures of the payment system in an effort to comply with regulations promulgated under this section, shall not be liable to any party for such action.

"(5) ENFORCEMENT.—

"(A) IN GENERAL.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

"(B) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in subsection (a)(2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

"(i) The extent to which the person is extending credit or transmitting funds knowing the transaction is in connection with an unlawful Internet pharmacy request.

"(ii) The history of the person in extending credit or transmitting funds knowing the transaction is in connection with an unlawful Internet pharmacy request.

"(iii) The extent to which the person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(iv) The feasibility that any specific remedy prescribed can be implemented by the person without substantial deviation from normal business practice.

''(v) The costs and burdens the specific remedy will have on the person.

''(f) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

''(1) identifying Internet pharmacy websites that are not licensed or that appear to be operating in violation of Federal or State laws concerning the dispensing of drugs;

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken

with respect to violations described in paragraph (1).''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as amended by section 2(b)) is amended by adding at the end the following:

''(ii) The sale of a prescription drug, or the ownership or operation of an Internet pharmacy, in violation of section 511.

''(jj) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 511.

''(kk) The acceptance of an advertisement from an Internet pharmacy by the provider of an interactive computer service, unless the provider has on file a copy of the license issued to the Internet pharmacy under section 511.''.

(c) LINKS TO ILLEGAL INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 511 relating to an illegal Internet pharmacy, the district courts of the United States and the United States courts of the territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, a website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

''(A) shall be available only after provision to the provider of notice and an opportunity to appear;

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 511; and

''(C) shall specify the provider to which the relief applies.''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate interim final regulations that are consistent with the Verified Internet Pharmacy Sites certification program developed by the National Association of Boards of Pharmacy to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The requirement of licensure under section 511 of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall take effect on the date determined by the Secretary of Health and Human Services but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(e) RETURN TO SENDER.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

''(p) UNLICENSED INTERNET PHARMACY.—If an Internet pharmacy is not licensed by the Secretary in accordance with section 511, any shipment of a prescription drug from such an Internet pharmacy to an individual shall be refused admission into the United States and the Secretary shall return the prescription drug, other than a prescription drug that is required to be destroyed, to the Internet pharmacy at the expense of the Internet pharmacy.

''(q) LICENSED INTERNET PHARMACY.—If a shipment of a prescription drug from an Internet pharmacy licensed by the Secretary in accordance with section 511 to an individual is refused admission into the United States, the Secretary shall—

''(1) return the prescription drug, other than a prescription drug that is required to be destroyed, to the Internet pharmacy at the expense of the Internet pharmacy; and

''(2) provide the individual and the Internet pharmacy with a written notice that informs the individual and the Internet pharmacy of the refusal and of the reason for the refusal.''.

**SEC. 5. ADMINISTRATIVE DETENTION AND TEMPORARY HOLD.**

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by adding after section 815 (as added by section 9) the following:

**''SEC. 816. ADMINISTRATIVE DETENTION.**

''(a) ADMINISTRATIVE DETENTION OF PRESCRIPTION DRUGS.—

''(1) DETENTION AUTHORITY.—

''(A) IN GENERAL.—An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any prescription drug that is found during an inspection, examination, or investigation under this Act conducted by the officer or qualified employee, if the officer or qualified employee has credible evidence or in-

formation indicating that the prescription drug presents a risk to the public health.

''(B) APPROVAL.—A prescription drug may be detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order of detention.

''(2) PERIOD OF DETENTION.—A prescription drug may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to commence an action under this subsection or section 302.

''(3) SECURITY OF DETAINED ARTICLE.—

''(A) IN GENERAL.—An order under paragraph (1) with respect to a prescription drug—

''(i) may require that the prescription drug be labeled or marked as detained; and

''(ii) shall require that the prescription drug be removed to a secure facility, as appropriate.

''(B) NO TRANSFER.—A prescription drug subject to an order under paragraph (1) shall not be transferred by any person from the place at which the prescription drug is ordered detained or from the place to which the prescrip-

tion drug is removed, until released by the Secretary or until the expiration of the detention period applicable under the order, whichever occurs first.

''(C) EFFECT OF PARAGRAPH.—This paragraph does not authorize the delivery of a prescription drug pursuant to the execution of a bond while the prescription drug is subject to an order under paragraph (1).

''(D) EFFECT OF BONDING PROVISION.—Section 801(b) does not authorize the delivery of a prescription drug pursuant to the execution of a bond while the prescription drug is subject to an order under paragraph (1).

''(4) APPEAL OF DETENTION ORDER.—

''(A) IN GENERAL.—With respect to a prescription drug detained under paragraph (1), any person that would be entitled to be a claimant for the prescription drug if the prescription drug were seized under paragraph (1) may appeal the order of detention to the Secretary.

''(B) ACTION BY THE SECRETARY.—Not later than 5 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the

order, and confirmation by the Secretary shall be considered to be a final agency action for purposes of section 702 of title 5, United States Code.

''(C) FAILURE TO ACT.—If, during the 5-day period specified in subparagraph (B), the Secretary fails to provide an opportunity for hearing or to confirm or terminate the order, the order shall be deemed to be terminated.

''(D) EFFECT OF COMMENCEMENT OF COURT ACTION.—The process under this paragraph for the appeal of an order under paragraph (1) with respect to a prescription drug terminates if the Secretary commences an action under subsection (a) or section 302 regarding the prescription drug.

''(b) EFFECT OF SECTION.—Nothing in this section applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

(b) TEMPORARY HOLD AT PORT OF ENTRY.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) (as amended by section 4(e)) is amended by adding at the end the following:

''(r) TEMPORARY HOLD AT PORT OF ENTRY.—

''(1) IN GENERAL.—If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that a prescription drug presents a risk to the public health, and the officer or qualified employee is unable to inspect, examine, or investigate the prescription drug upon the prescription drug's being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of the Treasury to hold the prescription drug at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the prescription drug as appropriate.

''(2) APPROVAL.—

''(A) IN GENERAL.—An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request.

''(B) DESIGNEES.—An official may not be designated under subparagraph (A) unless the official is the director of the district under this Act in which the prescription drug is located, or is an official senior to that director.

''(3) NOTIFICATION.—With respect to a prescription drug for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that the prescription drug, is being held under this subsection.

''(4) REMOVAL.—A prescription drug held under paragraph (1) shall be removed to a secure facility, as appropriate.

''(5) NO TRANSFER.—During the period in which a prescription drug is held under this subsection, the prescription drug shall not be transferred by any person from the port of entry into the United States for the prescription drug or from the secure facility to which the prescription drug has been removed.

''(6) EFFECT OF BONDING PROVISION.—Subsection (b) does not authorize the delivery of a prescription drug held under this subsection pursuant to the execution of a bond while the prescription drug is held under this subsection.

''(7) EFFECT OF SUBSECTION.—Nothing in this subsection applies to a prescription drug imported by an individual under section 812 or to a commer-

cial transaction conducted between an Internet pharmacy and an individual.''.

(c) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as amended by section 4(b)) is amended by adding at the end the following:

''(ll) The transfer of a prescription drug in violation of an order under section 816, or the removal or alteration of any mark or label required by the order to identify the prescription drug as detained.''.

**SEC. 6. SUSPENSION.**

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by adding after section 816 (as added by section 5) the following:

**''SEC. 817. SUSPENSION OF IMPORTATION.**

''(a) PRESCRIPTION DRUG.—If the Secretary determines that the importation of a particular prescription drug or particular dosage form of a prescription drug into the United States presents a risk to the public health, the Secretary may immediately order the suspension of the importation of the particular prescription drug or particular dosage form of the prescription drug.

''(b) SUSPENSION.—If the Secretary determines that a drug importation facility, pharmacy, Internet pharmacy, or wholesaler is engaged in a pattern of importing or offer-

ing for importation a prescription drug into the United States in violation of any of the requirements of this Act, the Secretary may immediately order the suspension of that person from engaging in the importation or offering for importation of prescription drugs into the United States.

''(c) CANADA OR PERMITTED COUNTRY.—If the Secretary determines that there is a pattern of prescription drugs being imported or offered for importation into the United States from Canada or a permitted country in violation of any of the requirements of this Act, the Secretary may immediately order the suspension of the importation or offering for importation into the United States of prescription drugs from Canada or that permitted country, as appropriate.

''(d) APPEAL OF SUSPENSION ORDER.—

''(1) IN GENERAL.—

''(A) PRESCRIPTION DRUGS.—With respect to the importation of a prescription drug, the importation of which is suspended under subsection (a), any person that would be entitled to be a claimant for the prescription drug may appeal the suspension order to the Secretary.

''(B) SUSPENDED PERSONS.—With respect to a drug importation facility, pharmacy, Inter-

net pharmacy, or wholesaler subject to a suspension order under subsection (b) or (c), the drug importation facility, pharmacy, Internet pharmacy or wholesaler may appeal the suspension order to the Secretary.

''(2) ACTION BY THE SECRETARY.—Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order.

''(3) FAILURE TO ACT.—If, during the 30-day period specified in paragraph (2), the Secretary fails to provide an opportunity for a hearing or to confirm or terminate the order, the order shall be deemed to be terminated.

''(e) NO JUDICIAL REVIEW.—An order under this section shall not be subject to judicial review.

''(f) EFFECT OF SECTION.—Nothing in this section applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as amended by section 5(c)) is amended by adding at the end the following:

''(mm) The importation or offering for importation of a prescription drug in violation of an order under section 817.''.

**SEC. 7. DEBARMENT FOR REPEATED OR SERIOUS PRESCRIPTION DRUG IMPORTATION VIOLATIONS.**

(a) DEBARMENT AUTHORITY.—

(1) PERMISSIVE DEBARMENT.—Section 306(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(1)) is amended—

(A) in subparagraph (B), by striking ''or'' at the end;

(B) in subparagraph (C), by striking the period at the end and inserting '', or''; and

(C) by adding at the end the following:

''(D) a person from importing a prescription drug or offering a prescription drug for importation into the United States.''.

(2) AMENDMENT REGARDING DEBARMENT GROUNDS.—Section 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended—

(A) by redesignating paragraph (4) as paragraph (5); and

(B) by inserting after paragraph (3) the following:

''(4) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; PRESCRIPTION DRUG IMPORTATION.—

''(A) IN GENERAL.—A person is subject to debarment under paragraph (1)(D) if—

''(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any prescription drug; or

''(ii) the person has engaged in a pattern of importing or offering for import a prescription drug that presents a risk to the public health.

''(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

(b) CONFORMING AMENDMENTS.—Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended—

(1) in subsection (b), by striking the subsection heading and inserting the following:

''(b) PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS; IMPORTS.—'';

(2) in subsection (c)(2)(A)(iii), by striking ''paragraph (2) or (3) of subsection (b)'' and inserting ''paragraph (2), (3), or (4) of subsection (b)''; and

(3) in subsection (d)(3)—

(A) in subparagraph (A)(i), by striking ''or paragraph (2)(A) or (3) of subsection (b)'' and inserting ''paragraph (2)(A), (3), or (4) of subsection (b)'';

(B) in clauses (i) and (ii) of subparagraph (B), by striking ''or subsection (b)(3)'' and inserting ''paragraph (3) or (4) of subsection (b)''; and

(C) in subparagraph (B)(ii), by striking ''or the food importation process, as the case may be'' and inserting '', or the food or prescription drug importation process, as the case may be''.

(c) EFFECTIVE DATE.—Section 306(l)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(l)(2)) is amended—

(1) in the first sentence, by striking ''and subsection (b)(3)(A)'' and inserting ''subsection (b)(3)(A), and subsection (b)(4)(A)''; and

(2) in the second sentence, by inserting '', subsection (b)(4)(B),'' after ''subsection (b)(3)(B)''.

(d) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as amended by section 6(b)) is amended by adding at the end the following:

''(nn) The importing or offering for importation into the United States of a prescription drug by, with the assistance of, or at the direction of a person debarred under section 306(b)(4).''.

(e) IMPORTATION BY DEBARRED PERSONS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) (as amended by section 5(b)) is amended by adding at the end the following:

''(s) IMPORTATION OF PRESCRIPTION DRUGS BY DEBARRED PERSONS.—

''(1) IN GENERAL.—If a prescription drug is imported or offered for importation into the United States, and the importer, owner, or consignee of the prescription drug is a person that has been debarred under section 306(b)(4), the prescription drug—

''(A) shall be held at the port of entry for the prescription drug; and

''(B) may not be delivered to the person.

''(2) EFFECT OF BONDING PROVISION.—Subsection (b) does not authorize the delivery of a prescription drug pursuant to the execution of a bond while the prescription drug is held under this subsection.

''(3) REMOVAL.—A prescription drug held under this subsection shall be removed to a secure facility, as appropriate.

''(4) NO TRANSFER.—During a period in which a prescription drug is held under this subsection, the prescription drug shall not be transferred by any person from the port of entry into the United States for the prescription drug or from the secure facility to which the prescription drug has been removed.

''(5) PERMISSIBLE DELIVERY.—A prescription drug held under this subsection may be delivered to a person that is not a debarred person under section 306(b)(4) if the person affirmatively establishes, at the expense of the person, that the prescription drug complies with the requirements of this Act, as determined by the Secretary.''.

**SEC. 8. REGISTRATION OF PRESCRIPTION DRUG IMPORTATION FACILITIES.**

(a) REGISTRATION OF CERTAIN IMPORTERS.—The Federal Food, Drug, and Cosmetic Act is amended by adding after section 813 (as added by section 2) the following:

**"SEC. 814. REGISTRATION OF CERTAIN IMPORTERS.**

''(a) IN GENERAL.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States, or in the dispensing of such drugs, shall register with the Secretary in accordance with this section.

''(b) REGISTRATION.—

''(1) IN GENERAL.—To register, the owner, operator, or agent in charge of a drug importation facility, pharmacy, Internet pharmacy, or wholesaler shall submit to the Secretary a registration that discloses—

''(A) the name and address of each drug importation facility, pharmacy, Internet pharmacy, or wholesaler at which, and all trade names under which, the registrant conducts business;

''(B) the name of each prescription drug to be imported into the United States by each

drug importation facility, pharmacy, Internet pharmacy, or wholesaler; and

''(C) the name and address of an agent for service of process in the United States.

''(2) CHANGE IN INFORMATION.—The registrant shall notify the Secretary in a timely manner of any change in the information provided under paragraph (1).

''(3) PROCEDURE.—Not later than 60 days after receipt of a completed registration under paragraph (1), the Secretary shall—

''(A) assign a registration number to each registered drug importation facility, pharmacy, Internet pharmacy, and wholesaler; and

''(B) notify the registrant of the receipt of the registration.

''(4) LIST.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a list of registrants.

''(B) AVAILABILITY.—The Secretary shall make the list described under subparagraph (A) and information submitted by a registrant under paragraph (1) available to the public on

an Internet website and through a toll-free telephone number.

''(c) ELECTRONIC FILING.—

''(1) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall provide for, and require the use of, electronic methods of submitting to the Secretary registrations required under this section and shall provide for electronic methods of receiving the registrations.

''(2) AUTHENTICATION.—In providing for the electronic submission of such registrations under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the registrant and validation of the data as appropriate.

''(d) EFFECT OF SECTION.—

''(A) AUTHORITY.—Nothing in this section authorizes the Secretary to require an application, review, or licensing process for a drug importation facility, pharmacy, or wholesaler.

''(B) IMPORTATION BY INDIVIDUALS.—Nothing in this section applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted

between an Internet pharmacy and an individual.''.

(b) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to carry out section 814 of the Federal Food, Drug, and Cosmetic Act (as added by this section).

(2) EFFECTIVE DATE.—The requirement of registration under section 814 of the Federal Food, Drug, and Cosmetic Act takes effect—

(A) on the effective date of the final regulations under paragraph (1); or

(B) if the final regulations have not been made effective as of the expiration of that period, on the date that is 1 year after the date of enactment of this Act, subject to compliance with the final regulations when the final regulations are made effective.

(c) IMPORTATION; FAILURE TO REGISTER.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) (as amended by section 7(e)) is amended by adding at the end the following:

''(t) FAILURE TO REGISTER.—

''(1) IN GENERAL.—If a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States has not submitted a registration to the Secretary in accordance with section 814, a prescription drug that is being imported or offered for importation into the United States shall not be delivered to the importer, owner, or consignee of the prescription drug until the drug importation facility, pharmacy, Internet pharmacy, or wholesaler is registered in accordance with section 814.

''(2) EFFECT OF SUBSECTION (b).—Subsection (b) does not authorize the delivery of the prescription drug pursuant to the execution of a bond while the prescription drug is held under this subsection.

''(3) REMOVAL.—A prescription drug held under this subsection shall be removed to a secure facility, as appropriate.

''(4) NO TRANSFER.—During the period in which a prescription drug is held under this subsection, the prescription drug shall not be transferred by any person from the port of entry into the United States for the prescription drug or from the

secure facility to which the prescription drug has been removed.''.

(d) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as amended by section 7(d)) is amended by adding at the end the following:

''(oo) The failure of a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States, or in the dispensing of such drugs, to register in accordance with section 814.''.

**SEC. 9. MAINTENANCE AND INSPECTION OF RECORDS FOR PRESCRIPTION DRUGS.**

The Federal Food, Drug, and Cosmetic Act is amended by adding after section 814 (as added by section 8) the following:

**''SEC. 815. MAINTENANCE AND INSPECTION OF RECORDS FOR PRESCRIPTION DRUGS.**

''(a) IN GENERAL.—The Secretary may by regulation establish requirements relating to the establishment and maintenance, for not longer than 2 years, of records by—

''(1) a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation of prescription drugs into the United States, or in the dispensing of such drugs; and

''(2) any person that processes, packages, distributes, receives, holds, or transports a prescription drug imported under this subchapter.

''(b) INSPECTION.—

''(1) IN GENERAL.—If the Secretary has reason to believe that a prescription drug imported under this subchapter presents a risk to the public health, the drug importation facility, pharmacy, Internet pharmacy, or wholesaler that imports the prescription drug, and each person that processes, packages, distributes, receives, holds, or transports the prescription drug shall, at the request of an officer or employee duly designated by the Secretary, permit the officer or employee, upon presentation of appropriate credentials and a written notice to such pharmacy or person, at reasonable times, within reasonable limits and in a reasonable manner, to have access to and copy all records relating to the prescription drug that are needed to enable the Secretary to determine whether the prescription drug presents a risk to the public health.

''(2) APPLICABILITY.—Paragraph (1) applies to all records maintained by or on behalf of the drug importation facility, pharmacy, Internet pharmacy, or wholesaler or such other person in any format

(including paper and electronic formats) and at any location.

''(c) PROTECTION OF SENSITIVE INFORMATION.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary under this section or any commercial or financial information that is privileged or confidential.

''(d) EFFECT OF SECTION.—Nothing in this section applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

**SEC. 10. ADVANCE NOTICE OF IMPORTED PRESCRIPTION DRUG SHIPMENTS.**

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (as amended by section 8(b)) is amended by adding at the end the following:

''(u) ADVANCE NOTICE OF IMPORTED PRESCRIPTION DRUG SHIPMENTS.—

''(1) IN GENERAL.—For purposes of enabling the Secretary to inspect at ports of entry a prescription drug that is being imported or offered for importation into the United States, the person importing or offering for importation the prescription drug

shall, in advance, provide to the Secretary a notice that includes—

"(A) the established name (as defined by section 502(e)), dosage form, and quantity of the prescription drug;

"(B) the name of the shipper of the prescription drug;

"(C) the name of the country from which the prescription drug originates;

"(D) the country from which the prescription drug is shipped;

"(E) the name of the port of entry of the prescription drug;

"(F) documentation from the drug importation facility located in Canada or a permitted country specifying—

"(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the facility from that source;

"(G) the lot or control number assigned to the prescription drug by the manufacturer of the prescription drug;

"(H) the name, address, telephone number, and professional license number of the drug importation facility located in Canada or a permitted country; and

"(I) certification from the drug importation facility located in a foreign country or from the manufacturer of the prescription drug that the prescription drug—

"(i) is approved for marketing in the United States and is not adulterated or misbranded; and

"(ii) meets all labeling requirements under this Act.

"(2) REFUSAL OF ADMISSION.—A prescription drug imported or offered for importation without submission of a notice under paragraph (1) shall be refused admission into the United States.

"(3) PERIOD OF ADVANCE NOTICE.—The period in which the notice under paragraph (1) is required to be made in advance of the time of the importation of a prescription drug or the offering of a prescription drug for importation shall be not less than 24 hours and not more than 5 days.

"(4) FAILURE TO PROVIDE NOTICE.—

''(A) IN GENERAL.—If a prescription drug is being imported or offered for importation into the United States and notice is not provided in advance in accordance with paragraph (1), the prescription drug shall be held at the port of entry for the prescription drug, and may not be delivered to the importer, owner, or consignee of the prescription drug, until the notice is submitted to the Secretary and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1).

''(5) EFFECT OF BONDING PROVISION.—Subsection (b) does not authorize the delivery of a prescription drug pursuant to the execution of a bond while the prescription drug is held under this subsection.

''(6) REMOVAL.—A prescription drug held under this subsection shall be removed to a secure facility, as appropriate.

''(7) NO TRANSFER.—During a period in which a prescription drug is held under this subsection, the prescription drug shall not be transferred by any person from the port of entry into the United States

for the article or from the secure facility to which the prescription drug has been removed.

''(8) EFFECT OF SUBSECTION.—

''(A) AUTHORITY.—This subsection does not limit the authority of the Secretary to obtain information under any other provision of this Act.

''(B) IMPORTATION BY INDIVIDUALS.—Nothing in this subsection applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) (as amended by section 8(c)) is amended by adding at the end the following:

''(pp) The failure to submit prior notice of the importation of a prescription drug in violation of section 801(s).''.

**SEC. 11. AUTHORITY TO MARK PRESCRIPTION DRUGS REFUSED ADMISSION INTO THE UNITED STATES.**

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) (as amended by

section 10(a)) is amended by adding at the end the following:

''(v) PRESCRIPTION DRUGS REFUSED ADMISSION.—

''(1) IN GENERAL.—If a prescription drug has been refused admission under subsection (a), other than such a prescription drug that is required to be destroyed, the Secretary may require the owner or consignee of the prescription drug to affix to the container of the prescription drug a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY'.

''(2) EXPENSES.—All expenses in connection with affixing a label under paragraph (1)—

''(A) shall be paid by the owner or consignee of the prescription drug; and

''(B) in default of such payment, shall constitute a lien against future importations made by the owner or consignee.

''(3) EFFECTIVE PERIOD.—A requirement under paragraph (1) with respect to a prescription drug remains in effect until the Secretary determines that the prescription drug has been brought into compliance with this Act.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection applies to a prescription drug imported

by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

(b) MISBRANDED PRESCRIPTION DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(w) If—

''(1) it is a prescription drug refused admission into the United States that fails to bear a label required by the Secretary under section 801(v);

''(2) the Secretary finds that the prescription drug presents a risk to the public health; and

''(3) on or after notifying the owner or consignee of the prescription drug that the label is required under section 801(v), the Secretary informs the owner or consignee that the prescription drug presents such a risk.''.

(c) RULE OF CONSTRUCTION.—With respect to a prescription drug that is imported or offered for importation into the United States, nothing in this section limits the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of prescription drugs refused admission under any other provision of law.

**SEC. 12. PROHIBITION OF PORT SHOPPING.**

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) (as amended by section 11(b)) is amended by adding at the end the following:

''(x) PORT SHOPPING.—

''(1) IN GENERAL.—If—

''(A) it is a prescription drug imported or offered for importation into the United States; and

''(B) the prescription drug has previously been refused admission under section 801(a);

unless the person reoffering the prescription drug affirmatively establishes, at the expense of the owner or consignee of the prescription drug, that the prescription drug complies with the applicable requirements of this Act, as determined by the Secretary.

''(2) EFFECT OF PARAGRAPH.—Nothing in this paragraph applies to importation of a prescription drug under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

**SEC. 13. AUTHORITY TO COMMISSION OTHER FEDERAL AND STATE OFFICIALS TO CONDUCT INSPECTIONS.**

Section 702(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(a)) is amended—

(1) by redesignating paragraphs (3) and (4) as paragraphs (5) and (6), respectively; and

(2) inserting after paragraph (2) the following:

''(3)(A) The Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal agency, may conduct examinations and investigations for the purposes of enforcing compliance with the amendments made by the Safe IMPORT Act of 2004 through the officers and employees of the other agency.

''(B) A memorandum of understanding under subparagraph (A) shall include—

''(i) provisions to ensure adequate training of officers and employees to conduct the examinations and investigations; and

''(ii) provisions regarding reimbursement that may, in the discretion of the head of the other agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this paragraph by the officers or employees of the other agency.

''(C) A memorandum of understanding under subparagraph (A) shall be effective only with respect to examinations or inspections at facilities or other

locations that are jointly regulated by the Secretary and the other agency.

''(D) Not later than 60 days after the end of each fiscal year in which the head a Federal agency carries out 1 or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the agency head shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on Energy and Commerce of the House of Representatives, a report that discloses, for that year—

''(i) the number of officers or employees that carried out 1 or more programs, projects, or activities under the memorandum of understanding;

''(ii) the number of additional articles that were inspected or examined as a result of the memorandum of understanding; and

''(iii) the number of additional examinations or investigations that were carried out pursuant to the memorandum of understanding.

''(4)(A) The Secretary may enter into a contract with a State to use the State Board of Pharmacy personnel of the State to conduct examinations

and inspection for the purpose of carrying out the amendments made by the Safe IMPORT Act of 2004.

''(B) A contract entered into under subparagraph (A) shall—

''(i) ensure adequate training of officers and employees to conduct the examinations and investigations; and

''(ii) be effective only with respect to examinations or inspections of drug importation facilities, pharmacies, Internet pharmacies, and wholesalers located in the State.''.

**SEC. 14. USER FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.**

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 397f et seq.) is amended by adding at the end the following:

**''PART 5—FEES RELATING TO PRESCRIPTION DRUG IMPORTATION**

**''SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.**

''(a) REGISTRATION FEE.—The Secretary shall establish a user fee program under which a drug importation facility, pharmacy, Internet pharmacy, or wholesaler reg-

istering with the Secretary under section 814 shall be required to pay a fee to the Secretary.

''(b) COLLECTION.—

''(1) COLLECTION ON INITIAL REGISTRATION.—A fee under this section shall be payable for the fiscal year in which the drug importation facility, pharmacy, Internet pharmacy, or wholesaler first registers under section 814 (or reregisters under that section if that person has withdrawn its registration and subsequently reregisters).

''(2) COLLECTION IN SUBSEQUENT YEARS.—After the fee is paid for that fiscal year, the fee shall be payable on or before October 1 of each year.

''(3) ONE FEE PER FACILITY.—The fee shall be paid only once for each drug importation facility, pharmacy, Internet pharmacy, or wholesaler registered for a fiscal year in which the fee is payable.

''(c) FEE AMOUNT.—The amount of the fee shall be determined each year by the Secretary and shall be based on the anticipated costs to the Secretary of enforcing the amendments made by the Safe IMPORT Act of 2004 in the subsequent fiscal year.

''(d) USE OF FEES.—The fees collected under this section shall be used, without further appropriation, to en-

force the amendments made by the Safe IMPORT Act of 2004.

''(e) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the beginning of each fiscal year beginning after September 30, 2004, for that fiscal year, registration fees.

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(2) FAILURE TO PAY.—If a registered drug importation facility, pharmacy, Internet pharmacy, or wholesaler subject to a fee under this section fails to pay the fee, the Secretary shall not permit the drug importation facility pharmacy, Internet pharmacy, or wholesaler to engage in importation or offering for importation prescription drugs under this Act until all such fees owed by that person are paid.

''(g) REPORTS.—

''(1) FEE ESTABLISHMENT.—Not later than 60 days before each fiscal year, the Secretary shall—

''(A) publish user fees under this section for that fiscal year;

''(B) hold a meeting at which the public may comment on the recommendations; and

''(C) provide for a period of 30 days for the public to provide written comments on the recommendations.

''(2) PERFORMANCE AND FISCAL REPORT.—Beginning with fiscal year 2005, not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(A) implementation of the user fee authority during the fiscal year; and

''(B) the use by the Secretary of the fees collected during the fiscal year for which the report is made.''.

**SEC. 15. ANTICOUNTERFEITING PROVISIONS.**

(a) REQUIRED RECORDS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by striking paragraph (1) and inserting the following: ''(1) A distributor of record that is engaged in the wholesale distribution of a drug subject to subsection (b), shall—

''(A) before each wholesale distribution of the drug—

"(i) with respect to each wholesale distribution of a drug subject to subsection (b), provide the person that receives the drug a statement that identifies the immediately previous distributor of record from which the drug was purchased; and

"(ii) with respect to a drug subject to subsection (b) that is imported to the United States, provide the person that receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug (including the date of transmission and the names and addresses of all parties to the transaction); and

"(B) create, maintain for 2 years, and make available to the Secretary for inspection at reasonable time, records that—

"(i) with respect to each wholesale distribution of a drug subject to subsection (b), identifies—

"(I) the immediately previous distributor of record from which the drug was purchased; and

"(II) the immediately subsequent distributor of record to which the drug was sold or otherwise transferred; and

"(ii) with respect to a drug subject to subsection (b) that is imported to the United States, identifies—

"(I) each previous distributor of record from which the drug was purchased or otherwise transferred; and

"(II) each subsequent distributor of record to which the drug was sold or otherwise transferred, to the extent feasible.".

(b) ELECTRONIC TRACK AND TRACE TECHNOLOGY.—Not later than December 31, 2007, the Secretary of Health and Human Services shall require the adoption and use of electronic track and trace technology for a prescription drug at the case and pallet level that will identify each sale, purchase, or trade of that case or pallet (including the date of transmission and the names and addresses of all parties to the transaction) .

(c) DISTRIBUTORS OF RECORD.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by striking paragraph (3) and inserting the following:

"(3) For the purposes of this subsection and subsection (d)—

"(A) the term 'distributor of record'—

"(i) means a person that takes title to or possession of a drug subject to subsection (b) from manufacture to retail sale;

"(ii) includes a person that manufacturers, processes, packs, distributes, receives, holds, imports, or offers for importation a drug subject to subsection (b); and

"(iii) does not include a transporter;

"(B) the term 'transporter' means the United States Postal Service, or equivalent governmental service of a foreign country, or a private carrier engaged in the business of transporting packages for hire; and

"(C) the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to other than the consumer or patient but not including an intracompany sale or distribution of a drug described in subsection (c)(3)(B).".

(d) ANTICOUNTERFEITING PROGRAMS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by adding at the end the following:

''(4) The Secretary shall—

''(A) establish a network to be known as the 'Counterfeit Alert Network' for the purpose of providing prompt notification to health professionals and the public of counterfeit drugs subject to subsection (b);

''(B)(i) develop and publish an Internet accessible–reference document to facilitate the positive identification by health professionals and regulatory agency personnel of prescription drugs marketed in the United States and Canada; and

''(ii) update the materials described under clause (i) quarterly and when a new permitted country is designated by the Secretary;

''(C) develop and publish educational materials to health professionals and consumers identify and report cases of counterfeit drugs subject to subsection (b);

''(D) develop and publish secure business practice guidelines for the sale and distribution of such drugs in cooperation with members of a drug supply chain; and

''(E) in cooperation with the National Association of Boards of Pharmacy, develop and publish re-

vised model rules for licensure of drug wholesalers for adoption by the States.''.

**SEC. 16. CONFORMING AMENDMENTS.**

(a) Section 1006 of the Controlled Substances Import and Export Act (21 U.S.C. 956) is repealed.

(b) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 301(aa)—

(A) by striking ''section 804'' and inserting ''subchapter B of chapter VIII''; and

(B) by striking ''such section'' each place it appears and inserting ''that subchapter'';

(2) in section 801(d)(1), by striking ''section 804'' and inserting ''subchapter B''; and

(3) by striking section 804.